REMARKS

I. Introduction.

Claims 1, 3-20, and 23-27 are pending and rejected to, as set forth below. Claims 1, 5-7, and 20 have been amended. Applicant respectfully submits that the claims as currently amended are in condition for allowance and respectfully requests reconsideration and further examination in view of the following.

II. Rejections under 35 U.S.C. §103.

Claims 1, 3-20 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,769,898 (*Jisander*) in view of U.S. Patent No. 6,030,218 (*Robinson*). Claims 1, 3-20 and 23-27 are further rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,769,898 (*Jisander*) in view of U.S. Patent No. 5,306,149 (*Schmid*). Applicant has reviewed the Office Action and respectfully submits that it fails to establish a *prima facie* case of obviousness, as explained below.

Independent claim 1 (as amended) recites:

A device to assist in regenerating bone, the device configured to at least partially surround the bone to be regenerated and defining a cavity next to the bone, the cavity for retaining a material next to the bone, the material comprising a substance for stimulating bone growth, wherein the device is comprised of wire mesh that includes:

(a) a plurality of first openings; and

(b) one or more second openings through which the material may be placed into the cavity, wherein each of the one or more second openings are larger than each of the plurality of first openings.

Applicant respectfully submits that none of the cited references, alone or in combination, disclose or suggest each of the limitations of independent claim 1. Applicant's invention as claimed in amended claim 1 comprises a device that at least partially surrounds the bone and is formed of a wire mesh as shown, for example, in figures 1, 2 and 3 of the specification. The

wire mesh is strong enough to protect the area where bone regeneration is to occur from chewing forces or tissue pressure, while at the same time being flexible enough to be bent to the shape required to fit around the jaw bone to form a cavity to retain material that stimulates bone growth. Further, the one or more second openings of Applicant's invention provides the advantage of allowing the placement of a material that stimulates bone growth after the device has been placed around a jaw bone. The plurality of first openings in the mesh, being smaller than the one or more second openings, help retain the material within the cavity.

In contrast to Applicants claimed invention, and as noted in the Office Action on Page 2, ¶5, *Jisander* does not disclose or suggest a device to assist in bone generation that is formed of a wire mesh as taught and claimed by Applicant. Furthermore, *Jisander* does not disclose a device with openings through which material may be placed into the cavity formed by the device, where the material is retained next to the bone where the device provides the protection necessary for bone regeneration. Thus, *Jisander* does not disclose each and every limitation of claim 1 as amended.

Moreover, the devices in *Jisander* do not provide as much protection to the bone regeneration site from chewing forces or tissue pressure as the claimed invention. For example, when the wire support of *Jisander* is covered with a flexible membrane the membrane will still be subject to deformation by chewing forces or tissue pressure that will inhibit bone regeneration. Likewise, when the wire loop device of *Jisander* is used to hold in place a bone transplant, it provides no protection from chewing forces or tissue pressure that can inhibit regeneration of the jaw bone around the transplant. The wire loop devices of *Jisander* are thus not able to provide the same degree of protection to the regenerating jaw bone provided by Applicant's invention.

Robinson also fails to disclose or suggest the limitations of independent claim 1, and in particular fails to disclose or suggest a wire mesh that includes (a) a plurality of first openings; and (b) one or more second openings through which a material may be placed into the cavity, wherein each of the one or more second openings are larger than each of the plurality of first openings.

Robinson discloses a sub-periosteally implantable prosthesis support structure, wherein "a bio-compatible fine mesh screen is fixed to and spans, tent-like, the framework to

substantially overlay the bone structure and space provided for subsequent bone growth." Abstract. *Robinson* does not disclose or suggest a wire mesh with different size openings, much less openings configured to allow a material to be placed within (and retained by) a cavity formed by the wire mesh. To the contrary, all of the figures in *Robinson* depicting the mesh indicate it is of uniform construction, e.g., "50x50 wires per inch weave." Figures 1-12; col. 5, lines 3-4. The apertures in the wire mesh of the *Robinson* device are also depicted (and described) as being very small, which would make it extremely difficult to place a material comprising a substance for simulating bone growth into a cavity formed by the wire mesh. Moreover, since the apertures in the wire mesh depicted in *Robinson* are all the same size, they would be ill-suited to simultaneously allow a material to be placed within the cavity **and** to retain that material within the cavity. As such, neither *Jisander* nor *Robinson*, alone in combination, teach or suggest each and every limitation of independent claim 1.

Schmid also fails to disclose or suggest each and every limitation of independent claim 1. In particular, *Schmid* fails to disclose or suggest a cavity defined by a wire mesh that includes (a) a plurality of first openings; and (b) one or more second openings through which a material may be placed into the cavity, wherein each of the one or more second openings are larger than each of the plurality of first openings.

The device in *Schmid* is directed to an implant for attaching a substitute tooth or dentures at the jaw. Col. 2, lines 40-42. The implant 11 is formed from a frame 3 that "comprises a base formed by lateral ribs 3a, longitudinal ribs 3b and six cross-ties 3c extending from the base edge and connected to the upper end of the central portion 2." Col. 3, lines 27-30. The frame 3 of the implant 11 is covered by a diaphragm 12 and clamped to the implant 11 "***in a fluid-tight manner***," forming a "***free space 17 between the cross-ties 3c of the frame 3 and the jawbone 10***." Col. 3, lines 35-49, col. 4, lines 9-10 (emphasis added). The diaphragm is made from "a porous polytetrafluoroethylene known under the trade name GORE-TEX or some other equivalent material" Col. 2, line 54-56. The GORE-TEX diaphragm prevents "the deposition of microorganisms in the region covered by the diaphragm, as well as the propagation of infection." Col. 2, lines 56-58. After being affixed to a patient's jaw, "[t]he inserted implant 11 is thereupon covered over, with exception of intermediate piece 13, by folding the gingival bindwebs 16 and the epithelium tissue 15 back into their proper place." Col 4, lines 5-8. The bone tissue "grows into the intermediate space covered by the diaphragm 12." Col. 4, lines 29-30.

Schmid clearly does not disclose a cavity defined by a wire mesh that includes (a) a plurality of first openings; and (b) one or more second openings through which a material may be placed into the cavity. The free space 17 where bone tissue grows, as *Schmid* explicitly states above, is defined by the diaphragm 12, which is placed between the frame 3 and tissue layers 15 and 16 as shown in Figure 2. The diaphragm 12 is not made from wire mesh, rather it is formed from GORE-TEX in order to seal off the free space 17 from microorganisms "in a fluid-tight manner." As such, the diaphragm 12 does not include any openings whatsoever, much less one or more openings through which a material could be placed into the free space 17. Additionally, most of the device in *Schmid* is covered by two layers of skin when implanted, rendering the device inaccessible to place a material in the free space 17, notwithstanding the microorganism-resistant seal by the diaphragm 12.

Applicant respectfully submits that neither *Jisander* nor *Schmid* (alone or in combination) disclose a cavity into which a material may be placed. Moreover, *Schmid* explicitly teaches away from such a modification by clearly stating that the free space 17 is tightly sealed by the GORE-TEX diaphragm 12 (and covered by two layers of skin) to prevent the introduction of microorganisms and infection. Modifying *Schmid* to allow a material to be added to the free space 17 would thus be counter to a key purpose of the device in *Schmid* (i.e. – sealing off the free space 17 to prevent infection).

In view of the foregoing, Applicant respectfully submits that the Office Action fails to establish a *prima facie* case of obviousness with regards to independent claim 1. The remaining claims in the application (claims 3-20 and 23-27) are dependent from claim 1 and are believed to be allowable for the same reasons.

CONCLUSION

In view of the amendments and arguments herein, reconsideration is respectfully requested. Applicant believes this case is in a condition for allowance, and respectfully requests withdrawal of the rejections and allowance of the pending claims. Applicant also reserves the right to prosecute any cancelled claims or additional claims, including claims of broader scope, in a continuation application.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to **Deposit Account No. 19-3878**.

The Examiner is invited to telephone the undersigned at the number listed below if it would in any way advance prosecution of this case.

Respectfully submitted,

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Date

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